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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,680	01/22/2002	Carl Johan Friddle	LEX-0301-USA	5215

24231 7590 09/17/2003  
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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 09/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/054,680	FRIDDLE ET AL	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Amendment filed 22 July 2003 (Paper No. 9) has been received and entered in full. Claims 1 and 2 have been amended and claims 5-8 have been added.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

3. The objection to the Specification as set forth at pp. 2 ¶3 in the previous Office Action (Paper No. 6, 22 January 2003) is *withdrawn* in view of Applicant's amendments (Paper No. 9, 22 July 2003).
4. The objection to claim 1 as set forth at pp. 2 ¶4 in the previous Office Action (Paper No. 6, 22 January 2003) is *withdrawn* in view of Applicant's amendments (Paper No. 9, 22 July 2003).

### ***Maintained Objections And/Or Rejections***

5. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth at pp. 2-14 ¶5-9 of the previous Office Action (Paper No. 6, 22 January 2003). It is noted that newly added claims 5-8 are included in the rejection was the grounds for rejecting newly added claims 5-8 are the same as the original claims 1-4.

6. Applicant traverses said rejection in their response (Paper No. 9, 22 July 2003) on the following grounds: **(a)** no working examples are required by statute, **(b)** first paragraph of Section 5 of the instant Specification satisfies the specificity requirement of 35 U.S.C. §101, **(c)** the “relevant literature” (Skolnick and Fetrow, Bork, Doerks *et al.*, Smith and Zhang, Brenner, Bork *et al.*) does not support the concept that function cannot be based on sequence and structural similarity, **(d)** the USPTO has repeatedly attempted to use said references as a basis to deny the utility of nucleic acid sequences, **(e)** Applicants submit that the overwhelming majority of those skilled in the art “believe” in bioinformatic prediction, **(f)** the Applicant discusses case law and the question of utility, **(g)** Exhibit B, C, D demonstrate that the utility asserted for SEQ ID NO: 1, 2, and 4 is credible, **(h)** the present invention has a number of substantial and credible utilities including two polymorphisms at position 1889 of SEQ ID NO: 1 and position 630 of SEQ ID NO: 2, and **(i)** Applicant discusses their opinion of the rejection of the asserted utility for polymorphisms of the claimed SEQ ID NO. Applicant’s arguments have been taken into consideration and are not found persuasive for the following reasons.

7. On “**(a)**”, Applicant is correct. However, the phrase “no working examples” in the previous Office Action (Paper No. 6, 22 January 2003) is a statement of fact by the Examiner that the instant Specification as filed does not have any *in vitro* data or art-accepted animal model data to establish a credible, specific, and substantial utility for SEQ ID NO: 1, 2, or 4 (see MPEP §2164.02).

8. On “**(b)**”, the information in the first paragraph of Section 5 of the instant Specification in fact establishes the contrary. No specificity is established as the transcripts are from a wide range of tissue sources, developmental stages, organs, and glands. Nor does the Specification specify

the species from which the samples were taken, the levels at which the transcripts are present, which SEQ ID NO is present, or what conditions the transcripts were found. Further the information is prophetic as it clearly states, "which may be expressed" (pp. 4 line 9). Thus no evidence is presented establish a specific utility only prophetic consideration of where the novel sequences may be found.

9. On "(c)", Applicant's review of the aforementioned references is noted. In summary, the references are used to support the Examiner's discussion of the underlying flaw of basing the structure and function of a novel sequence purely on sequence alignments and homology. Applicant's disagreement is noted. Nevertheless no evidence was presented to support a credible, specific, and substantial utility for SEQ ID NO: 1, 2, or 4.

10. On "(d)", the Applicant draws USPTO policy into question in the prosecution of the instant Application. The Examiner *declines* to comment (see MPEP §1701) and respectfully directs all questions and concerns on this matter to the Office of the Commissioner pursuant to 35 U.S.C. §3.

11. On "(e)", patent prosecution is a question of evidence not beliefs (see 37 C.F.R. §1.104). Currently, no persuasive evidence has been presented in the instant Application to support SEQ ID NO: 1, 2, and 4 having a credible, specific, and substantial utility as required by 35 U.S.C. §101. No beliefs are necessary to establish a credible, specific, and substantial utility nor was any requirement for Applicant's beliefs set forth in the previous Office Action (Paper No. 6, 22 January 2003).

12. On “(f)”, the case law recited by the Applicant is noted, however no evidence or argument was presented to support a credible, specific, and substantial utility for SEQ ID NO: 1, 2, or 4.

13. On “(g)”, the references and sequence homology results listed in Exhibits B, C, and D have been taken into consideration. These Exhibits show that the assertion that SEQ ID NO: 1, 2, and 4 are Na/Ca exchanger is credible. This is accepted by the Examiner. However, no evidence is presented by Exhibits B, C, and D other than sequence homology which is insufficient to establish a specific and substantial utility for the reasons set forth in the previous Office Action (Paper No. 6, 22 January 2003).

14. On “(h)”, the asserted utilities were taken into consideration in the previous Office Action (Paper No. 6, 22 January 2003). None of the asserted utilities were credible, specific, and substantial for the reasons set forth in the previous Office Action (Paper No. 6, 22 January 2003). This includes the polymorphisms designated by the Applicant because they are not shown to be related in any known disease, disorder, or condition.

15. On “(i)”, Applicant’s arguments in pp. 11-19 represents opinion and not evidence nor argument relevant to resolving the question of a credible, specific, and substantial utility for SEQ ID NO: 1, 2, and 4. The Examiner *declines* to comment pursuant to MPEP §1701. Applicant is respectfully reminded of the nature of business to be conducted with the USPTO (see 37 CFR §1.3 and §1.111).

16. Thus the rejection of claims 1-8 under 35 U.S.C. §101 is maintained.

17. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the reasons set forth at pp. 14 ¶10 of the previous Office Action (Paper No. 6, 22 January 2003). It is noted that newly added claims 5-8 are included in the rejection was the grounds for rejecting newly added claims 5-8 are the same as the original claims 1-4.

18. Applicant traverses said rejection in their response (Paper No. 9, 22 July 2003) on the following grounds: a credible, specific, and substantial utility has been established in argument pertaining to the rejection of the same claims under 35 U.S.C. §101. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

19. The rejection under 35 U.S.C. 101 was maintained. Therefore, Applicant's arguments were not found persuasive and thus are not persuasive for the rejection under 35 U.S.C. §112 ¶1.

20. Thus the rejection of claims 1-8 under 35 U.S.C. §112 ¶1 is maintained.

21. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth at pp. 14 ¶11 of the previous Office Action (Paper No. 6, 22 January 2003).

22. Applicant traverses said rejection in their response (Paper No. 9, 22 July 2003) on the following grounds: (a) the current amendment of claim 2 obviates the rejection and (b) the conditions are well known in the art and defined by references incorporated in the instant

Specification. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

23. On “(a)”, the current amendment fails to obviate the rejection as “highly stringent” is no better defined than “stringent”. The metes and bounds of “highly stringent” are no more clear in the prior art and the instant Specification than “stringent”.

24. On “(b)”, Current Protocols in Molecular Biology offers a wide range of definitions and conditions for stringency and as such no distinct and definite meaning can be placed on the limitation “highly stringent”.

25. Thus the rejection of claim 2 under 35 U.S.C. §112 ¶2 is maintained.

#### *Summary*

26. Claims 1-8 are rejected.

27. It is noted that Applicant's response contained several opinions not useful in resolving the question of a credible, specific, and substantial utility. Applicant is respectfully reminded of the nature of business to be conducted with the USPTO (see 37 CFR §1.3 and §1.111).

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
September 2, 2003

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER